Available for both men and postmenopausal women with osteoporosis by the Ontario formulary and most private drug plans[1]

Prolia® is indicated:[2]

- For the treatment of postmenopausal women with osteoporosis at high risk for fracture, defined as a history of osteoporotic fracture, or multiple risk factors for fracture; or patients who have failed or are intolerant to other available osteoporosis therapy. In postmenopausal women with osteoporosis, Prolia reduces the incidence of vertebral, nonvertebral and hip fractures.
- As a treatment to increase bone mass in men with osteoporosis at high risk for fracture, defined as a history of osteoporotic fracture, or multiple risk factors for fracture; or patients who have failed or are intolerant to other available osteoporosis therapy.
- As a treatment to increase bone mass in men with nonmetastatic prostate cancer receiving androgen deprivation therapy (ADT), who are at high risk for fracture.
- As a treatment to increase bone mass in women with nonmetastatic breast cancer receiving adjuvant aromatase inhibitor (AI) therapy, who have low bone mass and are at high risk for fracture.
- As a treatment to increase bone mass in women and men at high risk for fracture due to sustained systemic glucocorticoid therapy.
- As a treatment to increase bone mass in women and men at high risk for fracture who are starting or have recently started long-term glucocorticoid therapy.

Consult the Product Monograph at www.amgen.ca/Prolia_PM.pdf for important information relating to contraindications, warnings, precautions, adverse reactions, interactions, dosing and conditions of clinical use. The Product Monograph is also available by calling us at 1-866-502-6436.

CRITERIA:[1]

To increase bone mass in males and postmenopausal females with osteoporosis who meet the following criteria:[1]

High risk for fracture; and

Failed other available osteoporosis therapy (i.e. fragility fracture **OR** evidence of a decline in bone mineral density below pretreatment baseline levels) despite adherence for one year.	For whom oral bisphosphonates are contraindicated due to hypersensitivity **OR** abnormalities of the esophagus (e.g. esophageal stricture or achalasia) **OR** inability to stand or sit upright for at least 30 minutes.
♀ LU Code 428 ♂ LU Code 515	♀ LU Code 429 ♂ LU Code 516

High fracture risk is defined as:[1]
- A prior fragility fracture AND a moderate 10-year fracture risk (10% to 20%); OR
- A high 10-year fracture risk (≥20%); OR
- Where a patient's 10-year fracture risk is less than the thresholds defined above, a high fracture risk based on evaluation of clinical risk factors for fracture.

All above definitions are based on the CAROC or FRAX tool.

Notes:
- Use of the CAROC or FRAX tool may underestimate fracture risk in certain circumstances and may not include all risk factors.
- In all cases, patients on Prolia must not be receiving concomitant bisphosphonate therapy. Recommended dose of Prolia is a single SC injection of 60 mg, once every 6 months.

LU Authorization Period: Indefinite

CAROC=Canadian Association of Radiologists and Osteoporosis Canada; FRAX=Fracture Risk Assessment

Pr prolia® denosumab

PAAB

References: 1. Ontario Drug Benefit Formulary/Comparative Drug Index Edition 43. Accessed February 7, 2018. http://www.health.gov.on.ca/en/pro/programs/drugs/formulary43/summary_edition43_20180124.pdf. **2.** Prolia Product Monograph. Amgen Canada Inc., June 25, 2019.